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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/830,195	BUISER ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *16 and 32-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17- 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 1/23/07 is acknowledged. The election of the following species is also acknowledged: polymer as the link. Claims 1 – 48 are pending. Claims 32 – 48 have been withdrawn from consideration as being drawn to a non-elected invention. Claim 16 has been withdrawn from consideration as being drawn to a non-elected species. Claims 1 – 15 and 17 – 31 are readable upon the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 15 and 17 – 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to particles which have an interior region with a density of large pores and a surface region with a density of large pores, and the density of large pores of the interior region is greater than the density of pores at the surface region. The claim is unclear because of the recitation of the phrase "large pores," i.e. how large are the pores? What size of pores would be considered large? In addition, the recitation that the density of the large pores of the interior region is greater than the density of large pores at the surface region is unclear because the term "greater" is a relative term that renders the term ambiguous

because both the interior region and the surface region appear to contain large pores, especially since the claim recites two indefinite areas of the particle and it is unclear how it is to be determined where each of these areas starts and ends in order to ascertain the difference in pore densities.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5, 15, 17 – 23 and 25 – 31 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobsen *et al.* (US 6,530,934) in view of Lanphere *et al.* (US 2003/0185895).

The applied reference (Lanphere) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The device generally comprises a flexible elongated

filament having a linear sequence of beads disposed thereon. The beads may be fixedly connected to the filament. The string of beads may be configured to the exact length needed. The beads may be porous (abstract). The embolic device is used to occlude blood flow and/or initiate blood clotting upon introduction to the body via a catheter (column 1, lines 14 – 25). The string of beads includes a filament (i.e. a link) and beads. The beads have diameters from 0.002 inches to 0.0018 inches, and may be made of a variety of materials, including polymers, radioopaque polymers, metals. The string of beads may be comprised of beads of several different materials (column 4, lines 25 – 40). The filament can be a multi or monofilament polymer (column 5, line 21). The string of beads may be configured as a drug delivery device, wherein the beads are porous and contain a medicament for controlled release into the interior of the body (column 2, lines 44 – 47).

Jacobsen does not specifically recite that the porous beads have an interior and surface regions with a density of large pores, wherein the density of pores of the interior region is greater than that of the surface region.

Lanphere discloses a drug delivery device which is a substantially spherical polymer particle having an internal reservoir region including relatively large pores and a metering region substantially surrounding the reservoir region having fewer relatively large pores (paragraph 0004). A sustained, controlled-dosage release of a therapeutic agent can be achieved using the particles (paragraph 0010). The particles have a diameter in the range of 1 cm or less, e.g., 5 mm to 1 mm or less, e.g., about 1200 microns or less, and about 10 microns or more, e.g. about 400 microns or more and the

pores are about 50 or 35 to 0.01 micron. Preferably, the particles are classified in size ranges of about 500-700 microns, about 700-900 microns, or about 900-1200 microns. The particles have a mean diameter in approximately the middle of the range and variance of about 20% or less, e.g. 15% or 10% or less (paragraph 0025). The particles can be used in chemoembolization (paragraph 0066). The particles are suspended in a carrier fluid, which may include saline and a contrast solution (paragraph 0030).

Lanphere fails to recite that at least two particles are connected.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the porous particles of Lanphere as the porous beads in the embolic device comprised of a linear sequence of flexibly interconnected miniature beads, taught by Jacobsen, because both the embolic device of Jacobsen and the embolic particles of Lanphere are used for controlled release drug delivery (see Jacobsen column 2, lines 44 – 47). One would have been motivated to do so because Lanphere specifically teaches that a polymeric particle having an internal reservoir region including relatively large pores and a metering region having fewer relatively large pores controls the release of an agent from the particle, and are particularly useful for delivery of desired drug dosages for an extended period of time (see Lanphere paragraphs 0003 – 0010).

Claims 1, 2, 5, 15, 17 – 23 and 25 – 31 are rejected under 35 U.S.C. 103(a) as being obvious over Lanphere *et al.* (US 2004/0096662) in view of Jacobsen *et al.* (US 6,530,934).

The applied reference (Lanphere) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Lanphere discloses embolic particles which have a first density of pores in an interior region and a second density of pores at a surface region, and the first density is different from (i.e. greater than) the second density (paragraph 0004 and 0016). Compositions including embolic particles are used for occluding vessels in a variety of medical applications. The particles are suspended in a carrier fluid, which can include a

saline solution, a contrast agent or both (paragraph 0027). A plurality of particles can have a mean diameter of about 500 microns or less and/or about 10 microns or more. A plurality of particles can have a mean diameter of about 100 microns or more and/or a mean diameter of about 300 microns or less. A plurality of particles can have a mean diameter of about 300 microns or more (paragraph 0028).

Lanphere fails to recite that at least two particles are connected.

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The device generally comprises a flexible elongated filament having a linear sequence of beads disposed thereon. The beads may be fixedly connected to the filament. The string of beads may be configured to the exact length needed. The beads may be porous (abstract). The embolic device is used to occlude blood flow and/or initiate blood clotting upon introduction to the body via a catheter (column 1, lines 14 – 25). The string of beads includes a filament (i.e. a link) and beads. The beads have diameters from 0.002 inches to 0.0018 inches, and may be made of a variety of materials, including polymers, radioopaque polymers, metals. The string of beads may be comprised of beads of several different materials (column 4, lines 25 – 40). The filament can be a multi or monofilament polymer (column 5, line 21). The string of beads may be configured as a drug delivery device, wherein the beads are porous and contain a medicament for controlled release into the interior of the body (column 2, lines 44 – 47).

Jacobsen does not specifically recite that the porous beads have an interior and surface regions with a density of large pores, wherein the density of pores of the interior region is greater than that of the surface region.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the porous particles taught by Lanphere in an interconnected form, as taught in the device of Jacobsen because both the particles of Lanphere and the interconnected porous beads of Jacobsen are used for embolization. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Lanphere specifically teaches that hydrophilic particles which are used for occluding blood flow tend to become dislodged from the target site and migrate within the body potentially causing trauma or unwanted thrombosis, and that providing a device comprising a linear sequence of interconnected miniature beads is superior to individual particles because the device is less susceptible to migration within the body (column 1 – 2).

Claims 1, 2, 5, 8, 9, 15, 17 – 23, 25, 26, and 28 – 31 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobsen *et al.* (US 6,530,934) and Greene *et al.* (US 2002/0177855), in view of Smith *et al.* (US 5,888,930).

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The device generally comprises a flexible elongated filament having a linear sequence of beads disposed thereon. The beads may be fixedly connected to the filament. The string of beads may be configured to the exact

length needed. The beads may be porous (abstract). The embolic device is used to occlude blood flow and/or initiate blood clotting upon introduction to the body via a catheter (column 1, lines 14 – 25). The string of beads includes a filament (i.e. a link) and beads. The beads have diameters from 0.002 inches to 0.0018 inches, and may be made of a variety of materials, including polymers, radioopaque polymers, metals. The string of beads may be comprised of beads of several different materials (column 4, lines 25 – 40). The filament can be a multi or monofilament polymer (column 5, line 21). The string of beads may be configured as a drug delivery device, wherein the beads are porous and contain a medicament for controlled release into the interior of the body (column 2, lines 44 – 47), as set forth above.

Greene discloses an embolization device for occluding a body cavity which includes one or more elongated hydrophilic embolizing elements non-releasably carried along the length of an elongated filamentous carrier (abstract). The embolizing agents (micropellets) may be made of a macroporous polymeric material or a porous, environmentally-sensitive, expansile hydrogel (abstract and paragraphs 0085 – 0088). The carrier (i.e. link) is preferably a nickel/titanium wire, but may also be formed from a polymer (paragraph 0093). The carrier has a diameter of approximately 0.04 mm (i.e. 0.0015 inches) (paragraph 0092). The length of the carrier is variable depending on the size of the vascular site to be embolized (paragraph 0085). See also Figure 1. The device may be contained in saline solution (paragraph 0029). The devices may be used to deliver therapeutic agents (paragraph 0141).

Jacobsen and Greene do not specifically recite that the porous beads have an interior and surface regions with a density of large pores, wherein the density of pores of the interior region is greater than that of the surface region.

Smith discloses polymeric microporous beads having an anisotropic pore structure of large pores in the interior and smaller pores at the surface, the gradation of pore sizes between the interior and surface being continuous (abstract). It is noted that the instantly claimed particles do not prohibit the size of the interior pores being larger than that of the surface pores. It is interpreted that the particles of Smith demonstrate a larger pore density on the interior of the particle than on the surface, and accordingly that the particles of Smith are within the scope of those claimed (see Figure 1). The pores can be loaded with an active ingredient, and the particles are used as controlled-release of an active agent (column 1 – 2). The particles are generally spherical in shape, with diameters ranging from about 5 microns to about 5 mm (column 2, line 49).

Smith fails to teach particles which are connected.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the porous particles of Smith as the porous beads in the embolic device comprised of a linear sequence of flexibly interconnected miniature beads, taught by Jacobsen, or the embolic micropellets positioned along the length of a carrier, taught by Greene, because the embolic devices of Jacobsen or Greene and the particles of Smith are used for controlled release drug delivery (see Jacobsen column 2, lines 44 – 47). One would have been motivated to do so because Smith specifically teaches that microporous beads having an asymmetric pore structure are particularly

useful for delivery of active agents for an extended period of time (see Smith, column 2, lines 15 – 30).

Claims 1 – 15 and 17 – 26 and 28 – 31 are rejected under 35 U.S.C. 103(a) as being obvious over Jacobsen *et al.* (US 6,530,934) and Greene *et al.* (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), in further view of Mazzocchi *et al.* (US 6,605,102).

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The beads are porous and contain a medicament for controlled release into the interior of the body, as set forth above.

Greene discloses an embolization device for occluding a body cavity which includes one or more elongated, hydrophilic embolizing elements non-releasably carried along the length of an elongated filamentous carrier, as set forth above.

Jacobsen and Greene do not specifically recite that the porous beads have an interior and surface regions with a density of large pores, wherein the density of pores of the interior region is greater than that of the surface region. Jacobsen and Green also fail to specifically recite the length of the particle chain or the aspect ratio.

Smith discloses polymeric microporous beads having an anisotropic pore structure of large pores in the interior and smaller pores at the surface, the gradation of pore sizes between the interior and surface being continuous. The beads may vary in diameter from about 5 microns to about 5 mm, as set forth above, thus it is interpreted that a variety of sizes of particles may be used.

Smith fails to teach particles which are connected.

Mazzocchi teaches embolic devices which may have a variety of structures (abstract). The aspect ratio of the device ranges from about 1.0 to about 3.0, where an aspect ratio of 2.0 is preferred (column 11, lines 59+). The length of the devices may vary, but may be for example 25 mm (column 12, line 62). Mazzocchi does not teach that the embolic device is a particle chain.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the porous particles of Smith as the porous beads in the embolic device comprised of a linear sequence of flexibly interconnected miniature beads, taught by Jacobsen, or the embolic micropellets positioned along the length of a carrier, taught by Greene, because both the embolic devices of Jacobsen or Greene and the particles of Smith are used for controlled release drug delivery (see Jacobsen column 2, lines 44 – 47). One would have been motivated to do so because Smith specifically teaches that asymmetric microporous beads control the release of an agent from the particle, and are particularly useful for delivery of desired drug dosages for an extended period of time (see Smith, column 1 – 2). Regarding the specific dimensions of the devices, Greene also teaches an elongated carrier with embolic agents (micropellets) attached thereto, and teaches the width of the carrier (i.e. chain or link) to be within the claimed range, and also teaches that the length of the carrier can be varied depending on the vascular site to be embolized (column 11, line 20), and accordingly it would have been obvious to utilize chain with a variety of lengths (i.e. thereby effecting the aspect ratio), especially because Mazzocchi further shows that

embolic devices are generally known in the art to have length / width / aspect ratio dimensions within the claimed ranges.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER